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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,657	12/22/2004	Cinderella Christina Gerhardt	F7649(V)	9203

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EXAMINER	
BRADLEY, CHRISTINA	
ART UNIT	PAPER NUMBER
1654	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/519,657	GERHARDT ET AL.	
	Examiner	Art Unit	
	Christina Marchetti Bradley	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/12/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1-15 provide for the use of whey protein hydrolysate, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

3. Claims 1 and 3-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "enhanced" in claim 1 is a relative term which renders the claim indefinite. The term "enhanced" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. How is the enhanced feeling of satiety measured or defined?

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 1-15 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-12 and 14-18 are rejected under 35 U.S.C. 102(b) as being anticipated by O'Callaghan *et al.* (WO 93/04593). O'Callaghan *et al.* teach infant formula comprising whey protein hydrolysate (page 6, line 28 and examples 3 and 4). Infant formula is administered orally to infants and provides a feeling of satiety (limitation of instant claims 1 and 16) and is used to control body weight and/or calorie intake and to help adherence to a dietary plan (limitation of instant claims 2 and 17). Regarding claims 3, 4 and 12, the formula taught by O'Callaghan *et al.* is made from commercially available whey protein concentrate (WPC). WPC contains 56-60% beta-lactoglobulin and 18-24% alpha-lactalbumin for a ratio of 3.33:1 – 2.33:1. (See http://www.wheyprotein.com/sec6.html. Note that is proper to use an extra reference in a rejection under 35 U.S.C. 102 to show an inherent characteristic of the thing taught by the primary reference. See MPEP 2131.01.) Regarding claims 6, 10, 11 and 18, the whey protein hydrolysate is present a concentration of 77.15, 20.83 and 20.07% (see Tables 5, 7 and 9,

respectively). Regarding claims 7-9, 14-17, the baby formula is an edible composition to be used as a meal replacement (the formula replaces breast milk) as part of dietary and weight management program (the administration of formula is designed to promote healthy weight gain and growth). Regarding claims 9, the baby formula is a liquid produced from a soluble powdered product and is a dairy based product, a beverage and a pre-packed meal product (page 23, lines 7-8). Regarding claim 11, the compositions also contain potassium (see Tables 5, 7 and 9). Regarding claim 5, O'Callaghan *et al.* do not report the percent degree of hydrolysis of the whey protein hydrolysate but instead reports the molecular weight profile of the hydrolysate in Tables, 6, 8 and 10. Based on the molecular weight profile, it appears that the degree of hydrolysis falls within the claimed range of 1-20%.

8. O'Callaghan *et al.* do not teach that the whey protein hydrolysate induces cellular release of glucagons-like-peptides and cholecystokinins or the percentage of calories in the composition that come from the whey protein hydrolysate. Because the chemical structure of the baby formula taught by O'Callaghan *et al.* is identical to the claimed invention, there is a reasonable expectation that the species would meet this additional functional limitation. The discovery and characterization of properties of a known material do not make it novel (see MPEP § 2112). Furthermore, there is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference (see MPEP § 2112).

9. If the composition is physically the same, it must have the same functional properties. "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the

identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990) See MPEP § 2112.01. Examiner cannot however determine whether or not the baby formula taught by O'Callaghan *et al.* inherently possesses properties which anticipate or render obvious the claimed invention but has basis for shifting the burden of proof to applicant as in In re Fitzgerald, 619 F.2d 67, 205 USPQ 594 (CCPA 1980). See MPEP § 2112.

10. Claims 1-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Boza *et al.* (WO 99/49741, cited reference 3 on the Information Disclosure Statement mailed 12/12/2005). Boza *et al.* teach a method of administering to a mammal a nutritional composition which includes whey protein hydrolysate (page 4, lines 12-35). Regarding claims 3, 4, 12 and 13, the compositions taught by Boza *et al.* are made from commercially available whey protein concentrate (WPC). WPC contains 56-60% beta-lactoglobulin and 18-24% alpha-lactalbumin for a ratio of 3.33:1 – 2.33:1. (See http://www.wheyprotein.com/sec6.html. Note that is proper to use an extra reference in a rejection under 35 U.S.C. 102 to show an inherent characteristic of the thing taught by the primary reference. See MPEP 2131.01.) Regarding claim 5, the preferred degree of hydrolysis if 10-20% (page 4, line 27). Regarding claims 6, 10, 11 and 18, the whey protein hydrolysate is present a concentration of 30-50% by weight of the composition for infants and 10-20% of the energy (caloric intake) for adults (page 5, lines 1-9, Example 1 is 16%). Regarding claim 11, the nutritional composition includes a complete vitamin and mineral profile sufficient to supply 50-250% of the recommended daily allowance (page 6, lines 10-11 and table in Example 1 which recites the specific vitamins and mineral included in the liquid composition). Regarding claims 8-13, the nutritional composition may be in the form of a

soluble powder, a liquid concentrate, a ready-to-drink formula, a bar or breakfast cereal (page 6, lines 17-24). The nutritional composition may be administered to people who are not suffering from a disease or condition, including infants, and may be the sole source of nutrition or form a supplement (page 8, lines 2-6). Infant formula is administered orally to infants and provides a feeling of satiety (limitation of instant claims 1 and 16) and is used to control body weight and/or calorie intake and to help adherence to a dietary plan (limitation of instant claims 2 and 17).

11. Boza *et al.* do not teach that the whey protein hydrolysate induces cellular release of glucagons-like-peptides and cholecystokinins, an enhanced feeling of satiety or an improved perception of body image. Because the chemical structure of the baby formula taught by Boza *et al.* is identical to the claimed invention, there is a reasonable expectation that the species would meet this additional functional limitation. The discovery and characterization of properties of a known material do not make it novel (see MPEP § 2112). Furthermore, there is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference (see MPEP § 2112). Examiner cannot however determine whether or not the baby formula taught by Boza *et al.* inherently possesses properties which anticipate or render obvious the claimed invention but has basis for shifting the burden of proof to applicant as in In re Fitzgerald, 619 F.2d 67, 205 USPQ 594 (CCPA 1980). See MPEP § 2112.

12. Claims 1-4, 6, 8, 9, 13, and 16-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Reimer *et al.* (WO 01/37850, cited reference 7 on the Information Disclosure Statement mailed 12/12/2005). Reimer *et al.* teach the use of whey protein hydrolysates for the treatment or prevention of diabetes (see page 1, lines 5-6). These hydrolysates can induce a

release of glucagons-like peptide I and can be used to improve glucose homeostasis (see page 3, lines 3-4). The milk protein hydrolysate which is capable of inducing GLP-1 comprises proteins that are present in sweet or acid whey (see page 7, lines 20-21). The composition can be incorporated into food such as breakfast cereal flakes or bars, soy-based products, drinks, milk powders or confectionary bars (see page 10, lines 29-34). The composition can be a nutritional supplement for clinical nutrition (see page 10, line 33-34). The amount of whey protein is at least 0.01% by weight (see page 10, line 34). Regarding claims 3 and 13, the compositions taught by Reimer *et al.* are made whey protein. Whey protein contains 56-60% beta-lactoglobulin and 18-24% alpha-lactalbumin for a ratio of 3.33:1 – 2.33:1. (See http://www.wheyprotein.com/sec6.html. Note that is proper to use an extra reference in a rejection under 35 U.S.C. 102 to show an inherent characteristic of the thing taught by the primary reference. See MPEP 2131.01.)

13. Reimer *et al.* do not teach that the whey protein hydrolysate induces an enhanced feeling of satiety or an improved perception of body image. Because the chemical structure of the composition taught by Reimer *et al.* is identical to the claimed invention, there is a reasonable expectation that the species would meet this additional functional limitation. The discovery and characterization of properties of a known material do not make it novel (see MPEP § 2112). Furthermore, there is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference (see MPEP § 2112). Examiner cannot however determine whether or not the baby formula taught by Reimer *et al.* inherently possesses properties which anticipate or render obvious the claimed invention but has basis for shifting the burden of proof

to applicant as in In re Fitzgerald, 619 F.2d 67, 205 USPQ 594 (CCPA 1980). See MPEP § 2112.

Double Patenting

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

15. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

16. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

17. Claims 1-3, 5-10 and 12-18 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of copending Application No. 10/539,434. Although the conflicting claims are not identical, they are not patentably distinct from each other. Claim 1 of copending Application No. 10/539,434 is drawn to a method for of providing a sustained feeling of energy or maintaining or providing a feeling of well-being during the post-prandial period in a subject comprising administering to a human by means of an edible composition, an effective amount of a whey protein hydrolysate which is capable of inducing the cellular release of glucagon-like peptides and cholecystokinins. Regarding claims 3 and 12, claim 2 of copending Application No. 10/539,434 requires that the

WPH comprise hydrolysates of β-lactoglobulin or α-lactalbumin, or a mixture thereof.

Regarding claim 5, claim 3 of copending Application No. 10/539,434 requires that the WPH has a degree of hydrolysis in the range of 1 to 20. Regarding claims 6, 10, 13 and 18, claim 4 of copending Application No. 10/539,434 requires that the edible compositions comprise a total amount of from 0.1% to 80% by weight of the WPH based on the weight of the composition. Regarding claims 9 and 13, claim 6 of copending Application No. 10/539,434 requires that the edible composition is a meal replacement product that may be a ready to drink liquid, a liquid produced from a soluble powdered product, a soup, a dessert, a bar, a cereal based or pasta based or noodle based product, or, a soluble or dispersible powdered product. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

18. No claims are allowed.
19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christina Bradley whose telephone number is (571) 272-9044. The examiner can normally be reached on Monday through Friday, 8:30 A.M. to 5:00 P.M.
20. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.
21. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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